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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,312	12/04/2003	Dieter Hochrainer	821-011725-US(PAR)	9650
28501	7590	10/05/2005	EXAMINER	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			LEWIS, AARON J	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,312

Applicant(s)

HOCHRAINER, DIETER

Examiner

AARON J. LEWIS

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupte et al. ('294) in view of Hochrainer et al. ('118).

As to claim 1, Gupte et al. disclose a capsule chamber (15) for a powder inhaler in the form of a cavity open on two sides for accommodating a disposable capsule for pharmaceutically active inhalable compositions with a diameter for the inner cavity which is 1.1 to 2.5 times as great as the capsule diameter and a length, the length of the inner cavity of the capsule chamber, which is 1.02 to 2 times as great as the length of the capsule (col.4, lines 43-48).

The difference between Gupte et al. and claim 1 is the inner surface of the capsule chamber comprises spacers for the capsule in the form of raised elements.

Hochrainer et al. in a powder inhaler, teach the inner surface of the capsule chamber comprises spacers (3) for the capsule in the form of raised elements for the purpose of accommodating the capsules firmly enough to prevent them from falling out but on the other hand still permit easy removal so that parts of the capsules are not accidentally pulled apart on removal (col.1, lines 55-67).

It would have been obvious to modify the capsule chamber of Gupte et al. to provide them with spacers in the form of raised elements because it would have accommodated the capsules firmly enough to prevent them from falling out but on the other hand still permitted easy removal so that parts of the capsules are not accidentally pulled apart on removal as taught by Hochrainer et al..

As to claims 2 and 3, in Gupte et al. as modified by Hochrainer et al. the spacing of the outermost point of the spacers from the surface on which they are formed can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular spacing including 0.1 mm to 5 mm, preferably 0.5 mm to 2 mm. One of ordinary skill would have recognized that the spacing is dependent upon the typical capsule diameter and that such spacing need only be sufficient to hold the capsules firmly enough to prevent them from falling out yet allow a spent capsule to be removed without being pulled apart as taught by Hochrainer et al..

As to claims 4 and 5, Hochrainer et al. (figs.1-5) teach the spacers (3) are constructed as axial (e.g. axial ribs), transverse and/or helically extending ribs, as points, pins or undulating raised elements.

As to claim 6, Hochrainer et al. teach the ribs are not all at the same spacing (col.1, lines 65-66 and figs.3-5) from one another.

As to claim 7, Hochrainer et al. (figs.3 and 4) teach the ribs are triangular in cross section.

Claim 8 is substantially equivalent in scope to claim 1 and is included in Gupte et al. as modified by Hochrainer et al. for the reasons set forth above with respect to claim 1.

As to claims 9 and 10, Gupte et al. disclose the assembly is a revolver magazine (13) that has at least two capsule chambers arranged in a circular or spiral configuration with one another such that two adjacent capsule chambers are aligned parallel to one another, the base and top ends each being located in a plane (figs.1b,2b,2c).

As to claim 11, Gupte et al. as modified by Hochrainer et al. as discussed above with respect to claim 1 also teach an assembly comprising at least two capsule chambers (figs.1b,2b,2c), wherein the capsule chambers has (have) an air inlet opening and an air outlet opening (col.5, lines 56-58).

As to claim 12, Gupte et al. disclose the powder inhaler has a cutting device which is fitted with at least two sharp spikes and/or cutters (21), the spikes and/or cutters being capable of being inserted through openings (22) into the capsule chambers.

As to claim 13, Gupte et al. (fig.1a) disclose the following elements elements: a cup-shaped lower part (10) open at the top, a plate (e.g. bottom of housing as illustrated in fig.2a) which covers the opening (e.g. 18) of the lower part and perpendicularly to which is formed the capsule chamber of the type described above, a button (20) movable counter to a spring (28) is provided on the capsule chamber, comprising two sharp spikes or cutters (21) for opening the capsule, an upper part (11) with a mouth tube which is connected to the capsule chamber so as to be able to convey a powder aerosol and a lid, the elements being joined together by a common hinge element (12) such that they can be flipped back and forth relative to one another (fig.1a).

As to claim 14, Gupte et al. disclose the powder inhaler contains a magazine (13) of capsule chambers.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 15,17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al. (GB 2,356,842 A).

As to claim 15, Edwards et al. (figs.6A-M) disclose a capsule having an outer surface which has spacers in the form of raised elements.

As to claim 17, Edwards et al. (figs.6A-M) illustrate the spacers are constructed as axial, transverse and/or helically extending ribs, as points, pins or undulating raised elements.

As to claim 18, Edwards et al. (fig.6B) disclose the spacers are constructed as axial ribs.

As to claim 19, Edwards et al. (fig.6C) disclose the ribs are not all the same spacing from one another.

As to claim 20, Edwards et al. (fig.6F) disclose the ribs are triangular in cross section.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3743

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (GB 2,356,842 A).

As to claim 16, the spacing of the outermost point of the spacers from the surface on which they are formed on the capsule of Edwards et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular spacing including 0.1 mm to 5 mm, preferably 0.5 mm to 2 mm. One of ordinary skill would have recognized that the spacing sufficient to enable visually impaired patients to tactilely recognize a drug identification coding pattern and the spacing sufficient to enable a machine reader to recognize a drug identification coding pattern would have required different spacing.

Conclusion

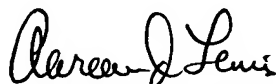
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant powdered inhalers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
September 23, 2005